



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Conflict of Interest

Conflict of Interest

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1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the requirements for conflict of interest (COI).

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

General Information

All key personnel involved in human subjects research at the University must have a financial interest disclosure form on file prior to the submission of an IRB application. If a financial conflict of interest is identified related to a specific project, it will be reviewed and managed as part of the review of the application by the IRB.

Financial conflicts of interests in human subjects research may present real or perceived risks to the rights and well-being of subjects. To ensure the integrity of research and its compliance with applicable laws and regulations, and the institution's legitimate interest in the financial health and economic viability of the enterprise, institutions should ensure that the responsibility for human subjects research does not overlap or coincide with interests that may be directly affected by the outcome of the research. Institutions should ensure that the functions and administrative responsibilities related to human subjects' research are separate from those related to investment, management, and technology licensing and other business interests of the Institution.

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A. Investigator/Research Team Conflicts

Conflicts of Interest may be either financial or non-financial, indirect or direct interests. Conflicts of interest are not always prohibited, but conflicts must be managed or eliminated so that they do not adversely affect participant protections or the credibility of the human research protections program.

When investigators have specific financial relationships or other non-financial interests, a disclosure must be submitted via the COI module in eCompliance. The COI committee will evaluate the conflict and those conflicts that have potential to impact human subjects research are flagged for the IRB Office. Additional disclosure and review information can be found here:

https://research.missouri.edu/compliance/conflict_of_interest/index.php

Investigator or other study staff conflicts:

Any investigator or other person responsible for the design, conduct, or reporting of research (including spouses and dependent children) that may have a conflict of interest with any proposed research will have that conflict evaluated and managed by the IRB.

Each investigator shall disclose all interests:

1. That would reasonably appear to directly and significantly affect the funded research or educational activities;
2. The following financial interests of all individuals involved in the design, conduct, or reporting of the research and their spouses and dependent children must be disclosed:
 - a. Ownership interest, stock options, or other financial interest related to the research of any amount.
 - b. Compensation or in kind remuneration related to the research of any amount.
 - c. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
 - d. Board or executive relationship related to the research, regardless of compensation.

This information must be disclosed:

- A. at the time the IRB proposal is submitted;
- B. on an annual basis during the project annual renewal; and
- C. immediately, as new conflicts arise.

If VA regulations apply, researchers must disclose conflicts of interest. This means disclosing to the IRB any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that might affect any aspect of the research, and complying with all applicable VA and other Federal requirements regarding conflict of interest.

Managing Research Conflicts of Interests

The IRB reviews research for conflicts of interest and has final authority for the management of the protocol/study under IRB review. The COI office provides

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access to monthly reports which highlight investigators with conflicts that are referred to the IRB. In addition, the integration of the COI and IRB modules within eCompliance provides the ability to flag all personnel who are added to an IRB application that have any known conflicts of interest.

Examples of how research conflicts of interest might be managed include the following:

1. Public disclosure of significant interests via the consent process and in publications and presentations;
2. Monitoring of all or a portion of the research by independent reviewers;
3. Modification of the research plan;
4. Disqualification from participation in all or a portion of the research; and/or
5. Divestiture of significant interests.

B. Board member and Consultant Conflict:

No IRB member, their spouse or dependent children, or consultant may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB.

An IRB member (their spouse and dependent children) or consultant is considered to have a conflicting interest when any of the following are true:

1. There is ownership interest, stock options, or other financial interest related to the research;
2. They receive compensation related to the research;
3. They have a proprietary interest related to the research;
4. There is an executive relationship related to the research;
5. Involvement in the design, conduct, or reporting of the research;
6. When assisting in development of the study;
7. When there is a personal or professional conflict with the other members listed on the study;
8. The IRB member or consultant believes that will be unable to impartially review a research protocol; and
9. The IRB member has identified him or herself for any other reason as having a conflicting interest.

IRB staff will remind members of COI policies at each meeting. Educational materials are available for IRB members to ensure their awareness of federal regulations and institutional policies regarding financial relationships and interests in human subjects' research.

Each board member has the responsibility of making the IRB staff aware of a conflict of interest. Prior to any review assignments, the IRB staff will check for any potential conflict of interest. The COI policy applies to each board member for all types of reviews.

IRB staff will ask consultants about conflicts prior to review assignment.

See the Board Meeting Procedures and Minutes SOP regarding board member and consultant conflicts during an IRB meeting.

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Additional information

The University of Missouri-Columbia has several policies governing COI:

- Collected Rules and Regulations on COI: https://www.umsystem.edu/ums/rules/collected_rules/personnel/ch330/330.015_policy_on_conflict_of_interest
- Collected Rules and Regulations on Institutional Conflicts of Interest: https://www.umsystem.edu/ums/rules/collected_rules/research/ch410/410.020_institutional_conflicts_of_interest_in_human_subjects_research

References:

Policy Revision Dates Prior to January 21, 2019:

June 1, 2004; December 12, 2005; December 1, 2006; June 10, 2010; July 1, 2011;
March 1, 2015; July 1, 2015; January 29, 2016; June 8, 2017